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**FROM** : Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP

**DATE** : August 31, 2006

**SUBJECT** : U.S. Patent Appln. Serial No. 10/608,660  
for *Pressure Actuated Valve with Improved Biasing Member*  
Our Ref.: 10123/00201

**NUMBER OF PAGES INCLUDING COVER : 23**

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Attorney Docket No. 10123/00201(03-007)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Weaver et al.  
Serial No. : 10/608,660  
Filed : June 27, 2003  
For : Pressure Actuated Valve with Improved Biasing Member  
Group Art Unit : 3761  
Examiner : Leslie R. Deak

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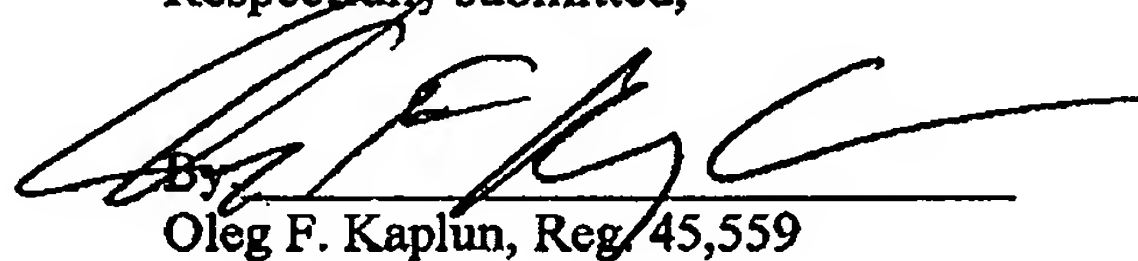
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By:  Oleg F. Kaplun, (Reg. No. 45,559)	Date: August 31, 2006

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Respectfully submitted,

Dated: August 31, 2006

  
By: \_\_\_\_\_  
Oleg F. Kaplun, Reg. 45,559

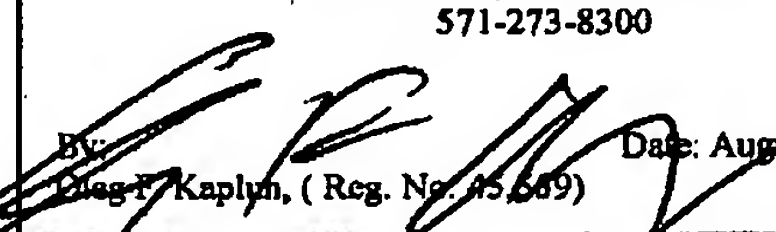
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Attorney Docket No. 10123/00201(03-007)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****RECEIVED  
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Applicant : Weaver et al.  
Serial No. : 10/608,660  
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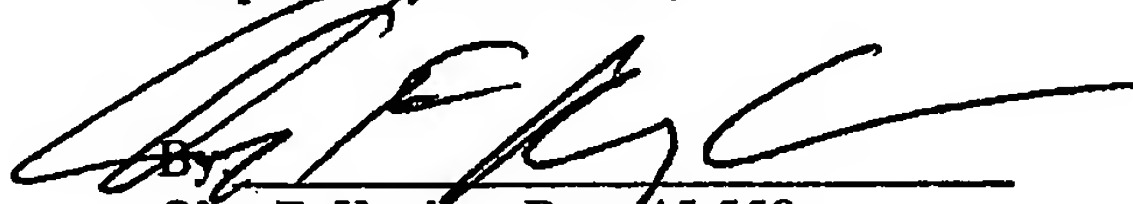
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Respectfully submitted,

Dated: August 31, 2006

  
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PATENT

Attorney Docket No.: 10123 - 00201

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:

**Karla Weaver et al.**

Serial No.: 10/608,660

Filed: June 27, 2003

For: PRESSURE ACTUATED VALVE  
WITH IMPROVED BLASING  
MEMBER

Group Art Unit: 3761

Examiner: Leslie R. Deak

**Board of Patent Appeals and  
Interferences**Mail Stop: Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Arlington, VA 22313-1450**APPEAL BRIEF UNDER 37 C.F.R. § 41.37**

In support of the Notice of Appeal filed July 6, 2006, and pursuant to 37 C.F.R. § 41.37, appellants present their appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1, 4-12, 15, 16 and 18-34 in the final Office Action dated March 7, 2006 and maintained in the Advisory Action dated July 3, 2006. The appealed claims are set forth in the attached Claims Appendix.

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1. Real Party in Interest

This application is assigned to Scimed Life Systems, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected, or have a bearing on the instant appeal.

3. Status of the Claims

Claim 2, 3, 13, 14 and 17 have been canceled. Claims 1, 4-12, 15, 16 and 18-34 have been rejected in the final Office Action and are the subject of the present appeal.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The present invention comprises a valve for controlling material flow through a catheter. (See Specification, page 2, lines 11-12). Independent claim 1 recites a first flexible member formed as a first sheet of polymeric material including first and second flaps separated from one another by a first slit, the first and second flaps moving, when subjected to a fluid pressure of at least a predetermined threshold level, to an open position so that material may flow past the first flexible member through a first lumen of the catheter, the first and second flaps remaining closed at all times when a fluid pressure exerted thereagainst is less than the threshold level to prevent flow through the first lumen. As described in the specification, a valve element includes a flexible disk formed of a polymeric material and having a slit therein formed of two moveable elements. (Id. at page 7, lines 17-28). The moveable elements are formed to remain in a closed position when not acted upon by fluid pressure and remain closed when subjected to naturally occurring anatomical influences such as the circulation of blood. (Id. at page 8, lines 6-

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19). The amount of pressure required to open the moveable elements is a function of material and geometric characteristics of the moveable elements, the slit and a flow passage containing the valve. (Id. at page 8, lines 20-27). Claim 1 also recites a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position. As described in the specification, a stiffening element is included in the valve element to control an amount of force biasing the movable elements to the closed position. In particular, coupling the stiffening element to a flexible disk or forming the stiffening element integrally therewith provides the valve element with more resistance to plastic deformation when the valve element is kept open for long periods of time. The stiffening element may be a ring, an embedded wire, etc. and may be formed of any substantially rigid material. (Id. at page 9, lines 1-10).

Independent claim 16 recites a valve housing for a catheter including a first end permanently coupled to a patient line, a distal end of which is to be implanted within a patient's body and a second end connectable to an external line; and a housing flow passage fluidly coupled to a flow passage of the patient line and selectively coupleable to a flow passage of the external line. As described in the specification, the present invention can be implemented in an implantable catheter coupled to a dialysis machine, with a distal end of the catheter fitting into a vein. (Id. at page 4, lines 8-21). Claim 16 also recites a valve mounted within the housing flow passage to selectively restrict flow of materials therethrough, the valve being formed as a sheet of polymeric material and including: first and second flaps separated from one another by a first slit in the sheet, the first and second flaps opening when a fluid pressure applied to the valve is at least a threshold pressure and remaining closed when the fluid pressure applied thereto is less than the threshold pressure. (Id. at page 8, lines 6-19; 20-27). Claim 16 further recites a first biasing member coupled to the valve, the biasing member biasing the first and second flaps to the closed position. (Id. at page 9, lines 1-10).

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6. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 1, 4-6, 8, 15 and 33 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,991,745 to Brown.
- II. Whether claims 29 and 31 are unpatentable under 35 U.S.C. § 103(a) as obvious over Brown.
- III. Whether claim 7 is unpatentable under 35 U.S.C. § 103(a) as obvious over Brown in view of U.S. Patent No. 6,621,557 to Cushman et al. ("Cushman").
- IV. Whether claims 9-12, 16, 18, 22-27, 30, 32 and 34 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,810,789 to Powers in view of Brown.
- V. Whether claims 19-21 and 28 are unpatentable under 35 U.S.C. § 103(a) as obvious over Powers in view of Brown and further in view of Cushman.

7. Argument

- I. The Rejection of Claims 1, 4-6, 8, 15 and 33 Under 35 U.S.C. § 102(b) as Anticipated by U.S. Patent No. 4,991,745 to Brown Should Be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 1, 4-6, 8, 15 and 33 under 35 U.S.C. 102(b) as anticipated by Brown. (See 3/7/06 Office Action, p. 3). Brown describes a disk-shaped valve including a slit surrounded by circular grooves 4 and a set of ribs 7 extending radially from a center area of the valve. (See Brown, col. 6, lines 1-14). The valve is integrally molded as a unitary element from a liquid silicone rubber. (Id. at col. 5, lines 42-50).



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**B. The Cited Reference Does Not Disclose a First Biasing Member Coupled to the First Flexible Member for Biasing the First and Second Flaps Toward the Closed Position as Recited in Claim 1**

Claim 1 of the present application recites a valve comprising "a first flexible member formed as a first sheet of polymeric material including first and second flaps separated from one another by a first slit, the first and second flaps moving, when subjected to a fluid pressure of at least a predetermined threshold level, to an open position so that material may flow past the first flexible member through a first lumen of the catheter, the first and second flaps remaining closed at all times when a fluid pressure exerted thereagainst is less than the threshold level to prevent flow through the first lumen" and "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position."

In the Final rejection, the Examiner stated that Brown discloses "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position." (See 3/7/06 Office Action, p. 3). The Examiner reaffirmed this position in the Advisory Action of July 3, 2006. (See 7/3/06 Advisory Action, ¶ 1). Specifically, the Examiner maintains that the ribs described by Brown constitute biasing members.

The ribs described by Brown are formed integrally with and from the same silicone material as the rest of the valve. Therefore, the ribs are indistinguishable from the center area from which the ribs extend. This can clearly be seen from the fact that the ribs have the same thickness as the center area. (See Brown, col. 6, lines 44-46). It would be improper, therefore, to view the ribs as discrete and separate elements. Rather, the ribs and the center area together (essentially the entire disk), form a unitary structure that should be viewed as a single element. Even if Brown does in fact, disclose "a first flexible member formed as a first sheet of polymeric material including first and second flaps separated from one another by a first slit," the



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ribs, being an integral part of the first flexible member, could not possibly constitute "a first biasing member *coupled* to the first flexible member," as recited in claim 1. This distinction is specifically noted in the specification of the present application. "[C]oupling a stiffening element to an otherwise flexible disk 110 (*or* forming a stiffening element integrally therewith) provides a valve element 100 including movable elements 118 more resistant to plastic deformation." (Specification, page 9, paragraph 19 lines 3-4). Thus, regardless of whether the ribs actually bias the slit closed or not, it is respectfully submitted that the ribs are not coupled to the valve as that term is used in this application.

In addition, the Appellants respectfully submit that the ribs do not constitute biasing members. Brown states that the ribs selectively stiffen and support the center area. (*Id.* at col. 6, lines 42-50). However, as the ribs are integrally formed of the same material (silicone) as the rest of the valve, the resistance to opening is a property of the valve itself. That is, the ability of the slit to close, or to resist opening forces, is inherent to the physical properties of the silicone itself. Brown was well aware of this and specifically formed the valve to include the ribs in order to take advantage of these properties. Thus, the ribs stiffen the valve area only relative to areas from which material has been removed—or, more accurately, areas from which material was deliberately left out in order to accommodate the grooves. Merely shaping the valve in a particular way does not impart any biasing ability to the valve in addition to that provided by the material of the valve itself.

Therefore, it is respectfully submitted that claim 1 is allowable for at least these reasons. Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. 102(b) of independent claim 1 and all the claims depending directly or indirectly therefrom (claims 4-6, 8, 15 and 33 ).

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II. The Rejection of Claims 29 and 31 Under 35 U.S.C.  
§ 103(a) as Obvious Over Brown Should Be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 29 and 31 under 35 U.S.C. 103(a) as obvious over Brown. (See 3/7/06 Office Action, p. 4). The Examiner stated, in support of the rejection, that Brown shows the invention substantially as claimed, except for the threshold pressure of the valve, but that it would have been obvious to one of ordinary skill in the art to alter the valve to achieve a desired threshold pressure. (Id.).

B. The Cited Reference Does Not Disclose a First Biasing Member Coupled to the First Flexible Member for Biasing the First and Second Flaps Toward the Closed Position as Recited in Claim 1

Claims 29 and 31 depend from independent claim 1. As discussed above, Brown neither discloses nor suggests "a first biasing member coupled to the first flexible member," as recited in claim 1. Thus, Appellants respectfully submit that claims 29 and 31 are allowable for at least the same reasons as claim 1.

In addition, claims 29 and 31 recite limitations relating the threshold pressure to pressures to which the valve will be subjected by anatomical influences. Brown's valve is described solely in conjunction with fluid dispensing packages and is unsuitable for use in medical devices. (See Brown, col. 1, lines 15-26). The valve described by Brown operates under pressures exerted by manual squeezing of the dispensing packages and is designed to remain closed at all times when not subject to this manually exerted pressure. (Id. at Figs. 9-16). Such manual pressures clearly exceed any which could possibly be exerted due to anatomical processes. As such, the Appellants respectfully submit that the valve described by Brown would not be successfully implemented in a catheter or any other medical device.

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For these reasons, the Appellants respectfully request that the Board overturn the rejection under 35 U.S.C. 103(a) of claims 29 and 31.

III. The Rejection of Claim 7 Under 35 U.S.C. § 103(a) as Obvious Over Brown in view of Cushman Should Be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claim 7 under 35 U.S.C. 103(a) as obvious over Brown in view of Cushman. (See 3/7/06 Office Action, pp. 4-5). In the rejection, the Examiner stated that Cushman discloses the use of a wire as a biasing element. (Id.).

B. The Cited References Do Not Disclose a First Biasing Member Coupled to the First Flexible Member for Biasing the First and Second Flaps Toward the Closed Position as Recited in Claim 1

Cushman describes an insert for a sandwich panel including a skin sheet 26 and a valve designed to remain sealed at all times regardless of a fluid pressure to which it is subjected. The valve is a disk located in a lower head portion 30 of the insert, against a washer 60. (See Cushman, Figs. 1 and 2). A spring 46 maintains the position of the insert by preventing lateral movement, keeping a top of the sandwich panel flush with the skin sheet 26. (See Cushman, col. 3, lines 70-75). The spring 46 is received in a groove portion 14 of the insert. (Id. at col. 3, lines 23-25). Because the spring 46 and the valve are disposed within separate portions of the insert, the spring 46 does not impose any force on the valve. There is no suggestion whatsoever that the spring 46 can act upon the valve in anyway. The only function of the spring 46 is to maintain the position of the insert. Cushman does not show or disclose a wire biasing element, or any kind of biasing element. Thus, the Appellants respectfully submit that Cushman is insufficient to cure the deficiencies of Brown and neither Brown nor Cushman, either alone or in combination, discloses or suggests "a first biasing member coupled to the first flexible member for biasing the

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first and second flaps toward the closed position," as recited in claim 1 and claim 7 (which depends from claim 1) is allowable. Accordingly, the Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. 103(a) of claim 7.

IV. The Rejection of Claims 9-12, 16, 18, 22-27, 30, 32 and 34 Under 35 U.S.C. § 103(a) as Obvious Over Powers in view of Brown Should Be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 9-12, 16, 18, 22-27, 30, 32 and 34 under 35 U.S.C. 103(a) as obvious over Brown in view of Cushman. (See 3/7/06 Office Action, p. 5). The Examiner has noted that Powers fails to disclose or suggest "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position," as recited in claim 1, from which claims 9-12 depend. (*Id.*).

B. The Cited References Do Not Disclose a First Biasing Member Coupled to the First Flexible Member for Biasing the First and Second Flaps Toward the Closed Position as Recited in Claim 1 and a First Biasing Member Coupled to the Valve, the Biasing Member Biasing the First and Second Flaps to the Closed Position as Recited in Claim 16

Powers describes a dual-lumen catheter with slit valves. (See Powers, col. 8, lines 10-19). A slit is located on a distal end of the catheter, extending between the exterior of the catheter and a lumen associated with the slit. (*Id.* at col. 8, lines 33-37). A valve is selectively operable between closed, inwardly open and outwardly open positions. The open positions are reached through radial flexure of the lumen wall in response to fluid pressure. (*Id.* at col. 11, line 9-col. 12, line 11). Absent from Powers, however, is any mention or suggestion of "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position," as recited in claim 1. As discussed above, Brown also does not teach or suggest this limitation. Thus, the Appellants respectfully submit that neither Powers nor Brown,

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either alone or in combination, discloses or suggests "a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position," as recited in claim 1.

In addition, it has been noted that Brown does not relate to medical devices and is incompatible with anatomical pressures to which the claimed invention relates. Powers relates to vascular access catheters, whereas Brown is directed to manually operated fluid dispensers. Furthermore, Powers describes a slit valve formed by cutting into a side wall of a catheter—not a valve comprising "a first flexible member formed as a first sheet of polymeric material," as recited in claim 1. Powers provides no suggestion whatsoever that the valve can be formed in any way other than by cutting a slit into the catheter wall. Even assuming that it were possible to introduce a disk into the catheter wall, such a valve would be unable to effect the radial flexure response as Powers intended. That is, the valve taught by Brown is not operable between inwardly and outwardly open positions. Thus, the Appellants respectfully submit that one skilled in the art would not be motivated to combine Brown with Powers. However, as described above, it is respectfully submitted that claims 9-12 are allowable even if these references are combined, as neither shows or suggests the recited biasing member. Accordingly, the Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. 103(a) of claims 9-12.

Independent claim 16 was also rejected under 35 U.S.C. § 103(a) as unpatentable over Powers in view of Brown. Claim 16 recites a valve housing for a catheter comprising, among other elements, "a valve mounted within the housing flow passage to selectively restrict flow of materials therethrough, the valve being formed as a sheet of polymeric material and including: first and second flaps separated from one another by a first slit in the sheet, the first and second flaps opening when a fluid pressure applied to the valve is at least a threshold pressure and remaining closed when the fluid pressure applied thereto is less than the threshold

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pressure” and “a first biasing member coupled to the valve, the biasing member biasing the first and second flaps to the closed position.” Thus, claim 16 contains substantially the same limitations as claim 1. Accordingly, the Appellants respectfully request that the Board overturn the Examiner’s rejection under 35 U.S.C. 103(a) of claim 16 and all claims depending therefrom (claims 18, 22-27, 30, 32 and 34).

V. The Rejection of Claims 19-21 and 28 Under 35 U.S.C. § 103(a) as Obvious Over Powers in view of Brown and Further in view of Cushman Should Be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 19-21 and 28 under 35 U.S.C. 103(a) as obvious over Powers in view of Brown and further in view of Cushman. (See 3/7/06 Office Action, p. 7).

B. The Cited References Do Not Disclose a First Biasing Member Coupled to the Valve, the Biasing Member Biasing the First and Second Flaps to the Closed Position as Recited in Claim 16

As previously discussed, neither Powers nor Brown teaches or suggests “a first biasing member coupled to the valve, the biasing member biasing the first and second flaps to the closed position,” as recited in claim 16. It has also been noted, with reference to claim 7, that Cushman does not teach or suggest “a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position.” Thus, the Appellants respectfully submit that Cushman does not cure the deficiencies of Powers and Brown and the Board should overturn the Examiner’s rejection under 35 U.S.C. 103(a) of claim 19-21 and 28, which depend from claim 16.



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8. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse all of the final rejections of the claims and indicate that claims 1, 4-12, 15, 16 and 18-34 are allowable.

Respectfully submitted,

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**CLAIMS APPENDIX**

1. A valve for controlling material flow through a catheter, comprising:  
a first flexible member formed as a first sheet of polymeric material including first and second flaps separated from one another by a first slit, the first and second flaps moving, when subjected to a fluid pressure of at least a predetermined threshold level, to an open position so that material may flow past the first flexible member through a first lumen of the catheter, the first and second flaps remaining closed at all times when a fluid pressure exerted thereagainst is less than the threshold level to prevent flow through the first lumen; and  
a first biasing member coupled to the first flexible member for biasing the first and second flaps toward the closed position.
2. (Cancelled)
3. (Cancelled)
4. The valve according to claim 1, wherein the first slit is substantially linear.
5. The valve according to claim 4, wherein the first biasing member extends around the first slit.
6. The valve according to claim 5, wherein the first biasing member is substantially rectangular.
7. The valve according to claim 1, wherein the first biasing member is formed of a wire embedded within the first flexible member.
8. The valve according to claim 4, wherein the flexible member is formed substantially as a

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disc and where the first slit extends substantially parallel to a major axis of the disc.

9. The valve according to claim 1, further comprising:

a housing in which the first flexible member is mounted, the housing comprising first and second lumens, the first flexible member being mounted within the first lumen and a second flexible member formed as a sheet of polymeric material being mounted within the second lumen, the second flexible member including third and fourth flaps remaining in a closed position at all times when a fluid pressure exerted thereagainst is lower than a further threshold level, the third and fourth flaps moving into an open position in which material may flow past the second flexible member through the second lumen when the fluid pressure thereagainst is at least the further threshold pressure; and

a second biasing member coupled to the second flexible member for biasing the third and fourth flaps toward the closed position.

10. The valve according to claim 1, wherein the first and second flaps are separated by first and second substantially parallel slits.

11. The valve according to claim 9, wherein the housing is adapted to couple to a first external line to the first lumen for supplying blood to a dialysis machine and to couple the second lumen to a second external line for receiving blood from the dialysis machine.

12. The valve according to claim 9, wherein the housing is a unitary part of the catheter.

13. (Cancelled)

14. (Cancelled)

15. The valve according to claim 1, wherein the first flexible member is formed as a silicone

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disc.

16. A valve housing for a catheter comprising:
  - a first end permanently coupled to a patient line a distal end of which is to be implanted within a patient's body and a second end connectable to an external line;
  - a housing flow passage fluidly coupled to a flow passage of the patient line and selectively coupleable to a flow passage of the external line; and
  - a valve mounted within the housing flow passage to selectively restrict flow of materials therethrough, the valve being formed as a sheet of polymeric material and including:
    - first and second flaps separated from one another by a first slit in the sheet, the first and second flaps opening when a fluid pressure applied to the valve is at least a threshold pressure and remaining closed when the fluid pressure applied thereto is less than the threshold pressure; and
    - a first biasing member coupled to the valve, the biasing member biasing the first and second flaps to the closed position.
17. (Cancelled)
18. The valve housing according to claim 16, wherein the first biasing member is embedded within the flexible sheet.
19. The valve housing according to claim 18, wherein the first biasing member is formed of at least one length of wire.
20. The valve housing according to claim 19, wherein the at least one length of wire extends around the first slit.
21. The valve housing according to claim 20, wherein the at least one length of wire

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comprises a plurality of unjoined wire segments.

22. The valve housing according to claim 18, further comprising a second biasing member, the first biasing member extending substantially parallel to the first slit on a first side thereof and the second biasing member extending substantially parallel to the first slit on a second side thereof opposite the first biasing member.

23. The valve housing according to claim 22, further comprising at least one third biasing member extending substantially perpendicular to the first slit and separated from an end of the first slit.

24. The valve housing according to claim 23, wherein the at least one third biasing member includes a pair of third biasing members extending adjacent to opposite ends of the first slit.

25. The valve housing according to claim 24, further comprising a pair of second slits extending substantially perpendicular to the first slit at opposite ends thereof to form an H-shaped arrangement of slits, wherein the third biasing members are radially outside the second slits with respect to the first slit.

26. The valve housing according to claim 20, further comprising a second slit extending substantially parallel to the first slit within the first biasing member.

27. The valve housing according to claim 16, further comprising a pair of second slits, each of the second slits extending away from a first end of the first slit at a predetermined angle and a pair of third slits, each of the third slits extending away from a second end of the first slit opposite the first end at a predetermined angle.

28. The valve housing according to claim 27, wherein the valve is formed as a sheet of

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flexible material and wherein the first biasing member comprises a wire embedded within the sheet of flexible material, the first biasing member extending around the first second and third slits.

29. The valve according to claim 1, wherein the threshold pressure is selected to be greater than pressures to which the valve will be subjected by anatomical influences.

30. The valve according to claim 16, wherein the threshold pressure is selected to be greater than pressures to which the valve will be subjected by anatomical influences.

31. The valve according to claim 1, wherein the threshold pressure is below a pressure at which anatomical structures connected to the device will be damaged.

32. The valve housing according to claim 16, wherein the threshold pressure is below a pressure at which anatomical structures connected to the device will be damaged.

33. The valve according to claim 1, wherein the first and second flaps open along a first direction in response to pressure along the first direction and along a second direction in response to pressure along the second direction, the first and second directions oriented opposite to each other along a longitudinal axis of the catheter.

34. The valve according to claim 16, wherein the first and second flaps open along a first direction in response to pressure along the first direction and along a second direction in response to pressure along the second direction, the first and second directions oriented opposite to each other along a longitudinal axis of the catheter.

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**EVIDENCE APPENDIX**

No evidence has been submitted herewith or is relied upon in the present appeal.

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**RELATED PROCEEDINGS APPENDIX**

There are no related proceedings and/or decisions which relate to the present  
appeal.